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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,693	09/25/2003	Chunhua Yan	CL000685-CON	4287

25748 7590 04/21/2005

CELERA GENOMICS

ATTN: WAYNE MONTGOMERY, VICE PRES, INTEL PROPERTY

45 WEST GUDE DRIVE

C2-4#20

ROCKVILLE, MD 20850

EXAMINER

FRONDA, CHRISTIAN L

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 04/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/669,693

Applicant(s)

YAN ET AL.

Examiner

Christian L. Fronda

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 17-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 17-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 September 2003 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. Claims 1-7 and 17-21 are pending and under consideration in this Office Action.
2. The claim objections recited in the previous Office Action have been withdrawn in view of applicants' amendment filed 01/21/2005.
3. The rejection of claims 4, 8, and 9 under 35 U.S.C. 112, second paragraph, has been withdrawn in view of applicants' cancellation of claims 8 and 9 and amendment to claim 4 filed in the amendment dated 01/21/2005.
4. The rejection of claims 1-4 and 7-9 under 35 U.S.C. 102(e) has been withdrawn in view of applicants' amendment filed 01/25/2005, where claim 1 no longer recites an isolated nucleic acid encoding a protein comprising the amino acid sequence of SEQ ID NO: 2.

Claim Rejections - 35 U.S.C. § 101

5. 35 U.S.C. 101 reads as follows:
Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.
6. Claims 1-7 and 17-21 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility.
Applicants' arguments filed 01/21/2005 have been fully considered but they are not persuasive. Applicants' position is that the claimed invention is supported by specific and substantial utilities, and one of ordinary skill in the art would know how to use the claimed invention. Applicants argue that despite the 50% homology of SQ ID NO: 2 to the amino acid sequence of a rabbit cytochrome p450 (Figure 2C of applicants' disclosure) one of skill in the art would reasonably be able to ascertain the use of the amino acid sequence given the disclosure and state of the art. Applicants argue that the claimed invention has "real world" uses such as a target to aid prevention of cancer caused by xenobiotic carcinogens. Applicants argue that cytochrome p450 proteins known in the art are important targets for drug action. The Examiner respectfully

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disagrees for reasons of record as supplemented below.

Although the examiner agrees with applicants' position that proteins in the art, which have been verified as cytochrome p450 proteins, are important targets for drug action, the examiner disagrees with applicants position that one of skill in the art would conclude that the claimed invention is a cytochrome p450 protein. While the Whisstock et al. reference (made of record in the previous Office Action) teaches that if an unknown protein shares a significant sequence similarity with a family of proteins of known function then a prediction of function can be reasonably proposed, Figure 2C of the disclosure, however, shows that Blast computer searches in the databases detected only a 50% identity between SEQ ID NO:2 and the amino acid sequence of a rabbit cytochrome p450. The examiner takes the position that one of skill in the art would conclude that this 50% identity to a rabbit cytochrome p450 is not a significant sequence similarity.

As stated in the previous Office Action, Whisstock et al. teach that protein function prediction from protein sequence and structure is useful but is not a substitute for laboratory experimentation. In view of the teachings of Whisstock et al. and the low percent homology between SEQ ID NO:2 and the amino acid sequence of a rabbit cytochrome p450, the only recognized utility of the claimed nucleic acid molecule and protein is to carry out further research to identify and/or reasonably confirm the specific biological function associated with the claimed nucleic acid molecule and protein.

Although applicants assert that the claimed invention has a "real world" use as a target to aid prevention of cancer caused by xenobiotic carcinogens, the specification does not disclose that the claimed protein asserted to be a cytochrome p450 has been actually targeted with any compound which would lead to treatment or prevention of any cancer caused by any xenobiotic carcinogen. One of skill in the art would conclude that further experimentation must be performed to reasonably confirm this asserted use. Utilities that require or constitute carrying out further research to identify and/or reasonably confirm a specific use are not substantial and do not provide a specific benefit. See MPEP 2107.01

Thus, the nucleic acid molecule consisting of the nucleotide sequence of SEQ ID NO: 1 lacks utility since the protein encoded having the deduced amino acid sequence of SEQ ID NO:2 has no specific or substantial asserted utility or a well established utility. Since the nucleic acid molecule consisting of the nucleotide sequence of SEQ ID NO: 1 lacks utility, then the genomic nucleotide sequence of SEQ ID NO: 3 which contains the nucleotide sequence of SEQ ID NO: 1 also lacks utility. Furthermore, since the nucleic acid molecules of SEQ ID NO: 1 and SEQ ID NO: 3 lack utility, then the claimed vectors and host cells and method of making the claimed protein using these claimed nucleic acid molecules also lack utility.

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7. Claims 3 and 19 are rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

As stated in the previous Office Action, claim 3, as written, does not sufficiently distinguish over host cells as they exist naturally because the claim does not particularly point out any non-naturally occurring differences between the claimed product and the naturally occurring product. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). New claim 19 which is directed toward a host cell "containing" a vector also has this defect

The claims should be amended to indicate the hand of the inventor, e.g., by reciting "an isolated host cell transformed with the vector". See MPEP 2105.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-7 and 17-21 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above and of record, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion

10. No claims are allowed.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

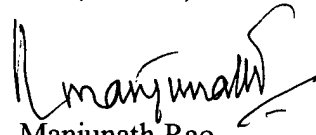
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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christian L. Fronda
Patent Examiner
Art Unit 1652


Manjunath Rao
Primary Patent Examiner
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